REMARKS

Reconsideration and withdrawal of the rejections are respectfully requested. The pending claims in the instant application are claims 1-27. No new matter has been added.

Rejection Under 35 U.S.C. §101

The Examiner rejected claims 1-27 under 35 U.S.C. §101 as allegedly not being supported by either a specific and substantial credible utility or a well established one. This rejection is respectfully traversed.

Applicants respectfully submit that the rejection is contrary to both the law and the United States Patent Office's own examination guidelines. The application of these standards to biotechnology inventions is discussed in the January 5, 2001 Federal Register Notice of the United States Patent Office's Utility Examination Guidelines. Section II.B.1(c)(1) and (2) of the January 5, 2001 "Utility Examination Guidelines" states "[a]n invention has a well-established utility if a person of ordinary skill would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties...), and the utility is specific, substantial, and credible" (66 FR 4, p. 1098). Moreover, "[a] patent examiner must accept a utility asserted by an applicant unless the Examiner has sound scientific reasoning to rebut the assertion" (66 FR 4, p. 1096). To establish a *prima facie* showing of lack of utility, "the Office must ... provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing ... the PTO must do more than merely question operability - it must set forth factual reasons which would lead one of skill in the art to question the objective truth of the statement of operability" (MPEP 2107.02(IV)). In addition, 66 FR 4, p. 1096 states that:

> When a class of proteins is defined such that the members share a specific, substantial, and credible utility, the reasonable assignment of a new protein to the class of sufficiently conserved proteins would impute the same specific, substantial, and credible utility to the assigned protein. . . . [A] 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient.

Upon reading the specification, one of skill in the art would immediately appreciate that zacrp5 is a member of the sufficiently conserved adipocyte complement related family of proteins and would reasonably impute that same specific, substantial, and credible utility to other members of the family.

The Examiner has provided no evidence or scientific basis to refute the assertions of utility for the polynucleotides of the present invention. The polynucleotide claims (claims 1-27) of the present invention is indeed supported by a specific asserted and well-established utility. Thus, Applicants submit that the Examiner has not established a *prima facie* showing of lack of utility, because it has not provided sound scientific reasoning to rebut the assertion of utility in the application and the evidence presented by Applicants therein. In view of the Examiner's apparent failure to note and evaluate this evidence, Applicants submit that a *prima facie* showing of no specific and substantial credible utility has not been made.

For the above reasons, Applicants respectfully submit that the invention recited in claims 1-27 is useful. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §101 are respectfully requested.

Rejections Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 1-27 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention. This rejection is respectfully traversed.

In light of the above remarks with respect to utility, reconsideration and withdrawal of the rejection of claims 1-27 under 35 U.S.C. §112, first paragraph, are respectfully requested.

The Examiner also rejected claims 1-27 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is respectfully traversed.

Applicants wish to point out that the enablement requirement is not precluded by the necessity for some experimentation, such as routine screening. The key word is "undue" not "experimentation." In re Angstadt, 190 USPQ 214, 219 (CCPA 1976). A considerable amount of experimentation is permissible if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. In re Jackson, 217 USPQ 804 (Bd. App. 1982).

Applicants respectfully submit that one of skill in the relevant art would be able to readily make and use the invention as claimed. Thus, upon reading the specification, one of skill in the art would know how to make and use a zacrp5 polynucleotide of the present invention without undue experimentation. Here the Examiner has offered no reason to doubt the truth of the statements in the specification.

Because a reasonable basis to question the enablement provided for the claimed invention was not provided in the Office Action, the burden of proof under 35 U.S.C. §112, first paragraph has not been satisfied, and a *prima facie* case of lack of enablement has not been made. "A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling supports." MPEP §2164.04. Reasons for uncertainty of the enablement are required even when there is no evidence in the record of operability without undue experimentation beyond the disclosed embodiments.

Accordingly, reconsideration and withdrawal of the rejection of claims 1-27 under 35 U.S.C. §112, first paragraph, are respectfully requested.

Summary

It is respectfully submitted that claims 1-27 are in condition for allowance, and notification to that effect is earnestly solicited. The Examiner is invited to contact Applicants' Agent at (206) 402-6540, if it is believed that prosecution of this application may be assisted thereby.

Respectfully Submitted,

Brian J. Walsh
Registration No. 45,543

Enclosures:
- Amendment Fee Transmittal (in duplicate)
- Petition and Fee for Extension of Time (in duplicate)
- Postcard